CLAIMS

We claim:

1. An anti-cancer composition for the purpose of treating at least one cell line of cancer in a mammalian patient comprising:

in at least one pharmaceutically acceptable carrier, a prophylactically effective amount of at least one selective COX-2 inhibitor, selected from the group of rofecoxib, celecoxib, etoricoxib, valdecoxib, and pharmaceutically acceptable flavanolignanes including silymarin, silibinin, silidianin, silicristin, dehydrosilybin, and phospholipid complexes of one of those flavanolignanes demonstrating selective COX-2 inhibition;

and a prophylactically effective amount of at least one HMG-CoA reductase inhibitor selected from the group of HMG-CoA reductase inhibitors particularly those known as statins, including lovastatin, simvastatin, pravastatin, compactin, atorvastatin calcium, cerivastatin sodium, fluvastatin sodium, and cholestin, to initially achieve a therapeutically effective change in cholesterol, and in combination with said selective COX-2 inhibitor to achieve a therapeutically effective change in progression of cancer.

2. An anti-cancer composition for the purpose of treating at least one cell line of cancer in a mammalian patient comprising:

in at least one pharmaceutically acceptable carrier, a prophylactically effective amount of at least one selective COX-2 inhibitor, selected from the group of rofecoxib, celecoxib, etoricoxib, valdecoxib, and pharmaceutically acceptable flavanolignanes including silymarin, silibinin, silidianin, silicristin, dehydrosilybin, and phospholipid complexes of one of those flavanolignanes demonstrating selective COX-2;

a prophylactically effective amount of at least one HMG-CoA reductase selected from the group of HMG-CoA reductase inhibitors known as statins, including lovastatin, simvastatin, pravastatin, compactin, atorvastatin calcium, cerivastatin sodium, fluvastatin sodium, and cholestin, to initially achieve a therapeutically effective change in cholesterol;

and a therapeutically effective amount of a glutathione pathway enhancing and

detoxifying compound in combination with said selective COX-2 inhibitor and said HMG-CoA reductase inhibitor to achieve a therapeutically effective change in progression of cancer.

3. An anti-cancer composition according to claim 2, further comprising:

said glutathione pathway enhancing and detoxifying compound being cystine.

4. An anti-cancer composition for the purpose of treating at least one cell line of cancer in a mammalian patient comprising:

in at least one pharmaceutically acceptable carrier, a prophylactically effective amount of at least one selective COX-2 inhibitor, selected from the group of rofecoxib, celecoxib, etoricoxib, valdecoxib, and pharmaceutically acceptable flavanolignanes including silymarin, silibinin, silidianin, silicristin, dehydrosilybin, and phospholipid complexes of one of those flavanolignanes demonstrating selective COX-2 inhibition;

a prophylactically effective amount of at least one HMG-CoA reductase inhibitor selected from the group of HMG-CoA reductase inhibitors particularly those known as statins, including lovastatin, simvastatin, pravastatin, compactin, atorvastatin calcium, cerivastatin sodium, fluvastatin sodium, and cholestin, to initially achieve a therapeutically effective change in cholesterol,

and in at least one of said at least one carrier, an excipient to augment immune function, said excipient being characterized by an ability to be a glutathione pathway enhancing and detoxifying compound, said composition and said prophylactically effective amounts being combined to achieve a therapeutically effective change in progression of cancer.

5. The anti-cancer composition according to claim 4, further comprising:

said excipient being cystine.

6. An anti-cancer composition for the purpose of treating at least one cell line of cancer in a mammalian patient comprising:

in at least one pharmaceutically acceptable carrier, a prophylactically effective amount of at least one selective COX-2 inhibitor, selected from the group of rofecoxib, celecoxib, etoricoxib, valdecoxib, and pharmaceutically acceptable flavanolignanes including silymarin, silibinin, silidianin, silicristin, dehydrosilybin, and phospholipid complexes of one of those flavanolignanes demonstrating selective COX-2 inhibition;

a prophylactically effective amount of at least one HMG-CoA reductase inhibitor selected from the group of HMG-CoA reductase inhibitors particularly those known as statins, including lovastatin, simvastatin, pravastatin, compactin, atorvastatin calcium, cerivastatin sodium, fluvastatin sodium, and cholestin, to initially achieve a therapeutically effective change in cholesterol,

and in at least one of said at least one carrier, a prophylactically effective amount of cystine to augment immune function which cystine is characterized by an ability to be a glutathione pathway enhancing and detoxifying compound, said composition and said prophylactically effective amounts being combined to achieve a therapeutically effective change in progression of cancer.

7. An anti-cancer composition for the purpose of treating at least one cell line of cancer in mammalian patient comprising:

in a pharmaceutically acceptable carrier, the combination of at least one HMG-CoA reductase inhibitor selected from the group of HMG-CoA reductase inhibitors known as statins, including lovastatin, simvastatin, pravastatin, compactin, atorvastatin calcium, cerivastatin sodium, fluvastatin sodium, and cholestin, beginning at a minimum recommended dose adjusted upward each six weeks by 10% within the therapeutic window of said HMG-CoA reductase inhibitor until LDL cholesterol has been lowered at least 10%; and

at least a minimum recommended dose of at least one selective COX-2 inhibitor, selected from the group of rofecoxib, celecoxib, etoricoxib, valdecoxib, and pharmaceutically acceptable flavanolignanes including silymarin, silibinin, silidianin, silicristin, dehydrosilybin, and phospholipid complexes of one of those flavanolignanes demonstrating selective COX-2 inhibition, said dose being adjusted upward each six weeks within the therapeutic window of said selective COX-2 inhibitor until at least two inflammatory response markers show therapeutic change: said at least two inflammatory response markers including upregulation of IL-12 and downregulation of IL-10; and

thereafter, until regression of tumor or a decrease in tumor progression, each said dose being adjusted upward on a six-week basis by at least 10% of the previous dose being given within the therapeutic window for each respective dose.

8. An anti-cancer composition for the purpose of treating at least one cell line of

cancer in mammalian patient comprising:

in a pharmaceutically acceptable carrier, the combination of at least one HMG-CoA reductase inhibitor selected from the group of HMG-CoA reductase inhibitors known as statins, including lovastatin, simvastatin, pravastatin, compactin, atorvastatin calcium, cerivastatin sodium, fluvastatin sodium, and cholestin beginning at a minimum recommended dose adjusted upward each six weeks by 10% within the therapeutic window of lovastatin until LDL cholesterol has been lowered at least 10%; and

at least a minimum recommended dose of at least one selective COX-2 inhibitor, selected from the group of rofecoxib, celecoxib, etoricoxib, valdecoxib, and pharmaceutically acceptable flavanolignanes including silymarin, silibinin, silidianin, silicristin, dehydrosilybin, and phospholipid complexes of one of those flavanolignanes demonstrating selective COX-2 inhibition, said dose being adjusted upward each six weeks within the therapeutic window of said selective COX-2 inhibitor until prophylactically effective upregulation of isoprostane and lipid peroxidation; and

thereafter, until regression of tumor or a decrease in tumor progression, each said dose being adjusted upward on a six-week basis by at least 10% of the previous dose being given within the therapeutic window for each respective dose.

9. An anti-cancer composition for the purpose of treating at least one cell line of cancer in mammalian patient comprising:

in a pharmaceutically acceptable carrier, the combination of at least one HMG-CoA reductase inhibitor selected from the group of HMG-CoA reductase inhibitors known as statins, including lovastatin, simvastatin, pravastatin, compactin, atorvastatin calcium, cerivastatin sodium, fluvastatin sodium, and cholestin, beginning at a minimum recommended dose adjusted upward each six weeks by 10% within the therapeutic window of said HMG-CoA reductase inhibitor until LDL cholesterol has been lowered at least 10%; and

at least a minimum recommended dose of at least one selective COX-2 inhibitor, selected from the group of rofecoxib, celecoxib, etoricoxib, valdecoxib, and pharmaceutically acceptable flavanolignanes including silymarin, silibinin, silidianin, silicristin, dehydrosilybin, and phospholipid complexes of one of those flavanolignanes demonstrating selective COX-2 inhibition, said dose being adjusted upward each six

weeks within the therapeutic window of said selective COX-2 inhibitor until at least two inflammatory response markers show therapeutic change: said at least two inflammatory response markers including upregulation of IL-12 and downregulation of IL-10; and

thereafter, until regression of tumor or a decrease in tumor progression, each said dose being adjusted upward on a six-week basis by at least 10% of the previous dose being given within the therapeutic window for each respective dose; and

and in at least one of said at least one carrier, a prophylactically effective amount of cystine to augment immune function which cystine is characterized by an ability to be a glutathione pathway enhancing and detoxifying compound, said composition and said prophylactically effective amounts being combined to achieve a therapeutically effective change in progression of cancer.

10. An anti-cancer composition for the purpose of treating at least one cell line of cancer in mammalian patient comprising:

in a pharmaceutically acceptable carrier, the combination of at least one HMG-CoA reductase inhibitor selected from the group of HMG-CoA reductase inhibitors known as statins, including lovastatin, simvastatin, pravastatin, compactin, atorvastatin calcium, cerivastatin sodium, fluvastatin sodium, and cholestin beginning at a minimum recommended dose adjusted upward each six weeks by 10% within the therapeutic window of lovastatin until LDL cholesterol has been lowered at least 10%; and

at least a minimum recommended dose of at least one selective COX-2 inhibitor, selected from the group of rofecoxib, celecoxib, etoricoxib, valdecoxib, and pharmaceutically acceptable flavanolignanes including silymarin, silibinin, silidianin, silicristin, dehydrosilybin, and phospholipid complexes of one of those flavanolignanes demonstrating selective COX-2 inhibition, said dose being adjusted upward each six weeks within the therapeutic window of said selective COX-2 inhibitor until prophylactically effective upregulation of isoprostane and lipid peroxidation; and

thereafter, until regression of tumor or a decrease in tumor progression, each said dose being adjusted upward on a six-week basis by at least 10% of the previous dose being given within the therapeutic window for each respective dose, and

and in at least one of said at least one carrier, a prophylactically effective amount of cystine to augment immune function which cystine is characterized by an ability to be

a glutathione pathway enhancing and detoxifying compound, said composition and said prophylactically effective amounts being combined to achieve a therapeutically effective change in progression of cancer.

11. The anti-cancer composition according to claims 1-10, further comprising: lipoic acid.

12. The anti-cancer composition according to claims 1-10, further comprising: at least one dietary supplement to maintain adequate levels of Vitamin C, Vitamin E and Selenium.

13. The anti-cancer composition according to claims 1-10, further comprising: lipoic acid; and

at least one dietary supplement to maintain adequate levels of Vitamin C, Vitamin E and Selenium.

14. A method of treating at least one cell line of cancer in a mammalian patient comprising:

Combining in a pharmaceutically acceptable carrier a prophylactically effective amount at least one selective COX-2 inhibitor, selected from the group of rofecoxib, celecoxib, etoricoxib, valdecoxib, and pharmaceutically acceptable flavanolignanes including silymarin, silibinin, silidianin, silicristin, dehydrosilybin, and phospholipid complexes of one of those flavanolignanes demonstrating selective COX-2 inhibition, within the therapeutic window for said selective COX-2 inhibitor;

and a prophylactically effective amount of at least one HMG-CoA reductase inhibitor selected from the group of HMG-CoA reductase inhibitors known as statins, including lovastatin, simvastatin, pravastatin, compactin, atorvastatin calcium, cerivastatin sodium, fluvastatin sodium, and cholestin, to initially achieve a therapeutically effective change in cholesterol, and in combination with said selective COX-2 inhibitor to achieve a therapeutically effective change in progression of cancer.

15. The method according to claim 14, further comprising the step:

incorporating in at least one of said at least one carrier an excipient to augment immune function, said excipient being characterized by an ability to be a glutathione pathway enhancing and detoxifying compound.

16. The method according to claim 15, further comprising:

said excipient being cystine.

17. A method of treatment of at least one cell line of cancer in a mammalian patient comprising:

administering at least a minimum recommended dose of in a pharmaceutically acceptable carrier;

administering at least a minimum recommended dose of rofecoxib in a pharmaceutically acceptable carrier in order to achieve a therapeutic change in cancer.

18. The method according to claim 17, further comprising the step:

incorporating in at least one of said at least one carrier an excipient to augment immune function, said excipient being characterized by an ability to be a glutathione pathway enhancing and detoxifying compound.

19. The method according to claim 18, further comprising:

said excipient being cystine.

20. A method of treatment of at least one cell line of cancer in a mammalian patient comprising:

administering a dose of lovastatin beginning at 10mg in daily amount in a pharmaceutically acceptable carrier;

administering a dose of rofecoxib beginning at 12.5 mg in daily amount in a pharmaceutically acceptable carrier,

adjusting said dose of lovastatin upward after six weeks within the therapeutic window of lovastatin until LDL cholesterol has been lowered at least 10%;

adjusting said dose of rofecoxib upward each six weeks within the therapeutic window for rofecoxib until prophylactically effective upregulation of isoprostane and lipid peroxidation; and

thereafter, until regression of tumor or a decrease in tumor progression, adjusting both doses upward on a six-week basis by at least 10% of the previous dose being given within the therapeutic window for each of rofecoxib and lovastatin.

21. The method according to claim 20, further comprising:

Combining a therapeutically effective amount of a glutathione pathway enhancing and detoxifying compound in combination with said rofecoxib and lovastatin to achieve a therapeutically effective change in progression of cancer.

22. The method according to claim 21, further comprising:

said glutathione pathway and detoxifying compound being cystine.

23. A method of treatment of at least one cell line of cancer in a mammalian patient comprising:

administering a dose of lovastatin beginning at 10mg in daily amount in a pharmaceutically acceptable carrier;

administering a dose of rofecoxib beginning at 12.5 mg in daily amount in a pharmaceutically acceptable carrier,

adjusting said dose of lovastatin upward after six weeks within the therapeutic window of lovastatin until LDL cholesterol has been lowered at least 10%;

adjusting said dose of rofecoxib upward each six weeks within the therapeutic window for rofecoxib until at least two inflammatory response markers, tested each six weeks, show therapeutic change: said at least two inflammatory response markers including upregulation of IL-12 and downregulation of IL-10; and

thereafter, until regression of tumor or a decrease in tumor progression, adjusting both doses upward on a six-week basis by at least 10% of the previous dose being given within the therapeutic window for each of rofecoxib and lovastatin.

24. The method according to claim 23, further comprising:

Combining a therapeutically effective amount of a glutathione pathway enhancing and detoxifying compound in combination with said rofecoxib and lovastatin to achieve a therapeutically effective change in progression of cancer.

25. The method according to claim 24, further comprising:

said glutathione pathway and detoxifying compound being cystine.

26. The method according to claims 14–25, further comprising:

administering lipoic acid.

27. The method according to claims 14–25, further comprising:

administering dietary supplements to maintain adequate levels of Selenium, Vitamin C and Vitamin E.

28. The method according to claims 14-25, further comprising:

administering lipoic acid; and

administering dietary supplements to maintain adequate levels of Selenium,

Vitamin C and Vitamin E.

29. A method of manufacturing an anti-cancer combination comprising the following steps:

incorporating in at least one pharmaceutically carrier for cancer patients at least the lowest dose in the therapeutic window at least one HMG-CoA reductase inhibitor selected from the group of HMG-CoA reductase inhibitors particularly those known as statins, including lovastatin, simvastatin, pravastatin, compactin, atorvastatin calcium, cerivastatin sodium, fluvastatin sodium, and cholestin; and

incorporating in at least one pharmaceutically acceptable carrier for cancer patients at least the lowest dose in the therapeutic window of at least one selective COX-2 inhibitor, selected from the group of rofecoxib, celecoxib, etoricoxib, valdecoxib, and pharmaceutically acceptable flavanolignanes including silymarin, silibinin, silidianin, silicristin, dehydrosilybin, and phospholipid complexes of one of those flavanolignanes demonstrating selective COX-2 inhibition.

30. A method of manufacturing an anti-cancer combination comprising the following steps:

incorporating in at least one pharmaceutically carrier for cancer patients at least the lowest dose in the therapeutic window at least one HMG-CoA reductase inhibitor selected from the group of HMG-CoA reductase inhibitors particularly those known as statins, including lovastatin, simvastatin, pravastatin, compactin, atorvastatin calcium, cerivastatin sodium, fluvastatin sodium, and cholestin; and

incorporating in at least one pharmaceutically acceptable carrier for cancer patients at least the lowest dose in the therapeutic window of at least one selective COX-2 inhibitor, selected from the group of rofecoxib, celecoxib, etoricoxib, valdecoxib, and pharmaceutically acceptable flavanolignanes including silymarin, silibinin, silidianin, silicristin, dehydrosilybin, and phospholipid complexes of one of those flavanolignanes demonstrating selective COX-2 inhibition; and

incorporating in at least one of said at least one carrier an excipient to augment immune function, said excipient being characterized by an ability to be glutathione pathway enhancing and detoxifying compound.

31. The method according to claim 30, further comprising:

said excipient being cystine.

32. The method of manufacturing according to claims 29-31, further comprising:
incorporating lipoic acid.

33. The method according to claims 29–31, further comprising:
incorporating dietary supplements to maintain adequate levels of Selenium, Vitamin C and Vitamin E.

34. The method according to claims 29-31, further comprising:
incorporating lipoic acid; and
incorporating dietary supplements to maintain adequate levels of Selenium, Vitamin C and Vitamin E.